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HEALTH CARE TECHNOLOGY

Healthcare technology and technology assessment

James H. Herndon · Raymond Hwang · K. H. Bozic

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Abstract New technology is one of the primary drivers for increased healthcare costs in the United States. Both physician and industry play important roles in the development, adoption, utilization and choice of new technologies. The Federal Drug Administration regulates new drugs and new medical devices, but healthcare technology assessment remains limited. Healthcare technology assessment originated in federal agencies; today it is decentralized with increasing private sector efforts. Innovation is left to free market forces, including direct to consumer marketing and consumer choice. But to be fair to the consumer, he/she must have free knowledge of all the risks and benefits of a new technology in order to make an informed choice. Physicians, institutions and industry need to work together by providing proven, safe, clinically effective and cost effective new technologies, which require valid pre-market clinical trials and post-market continued surveillance with national and international registries allowing full transparency of new products to the consumer—the patient.

Keywords Technology · Assessment · Costs · Clinical trials

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J. H. Herndon (✉) · R. Hwang
Department of Orthopaedic Surgery, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 617-367-5117, USA
e-mail: jherndon@partners.org

K. H. Bozic
Department of Orthopaedic Surgery and Institute for Health Policy Studies, School of Medicine, University of California, San Francisco, CA, USA

Introduction

Heathcare technology continues to advance at remarkable rates and its assessment continues to lag significantly. This paper reviews healthcare technology in the United States today: its rising costs, its impact on quality, some of the new emerging technologies, and how new technologies are introduced and adopted by healthcare providers. The important aspects of healthcare technology assessment will be emphasized, discussing physician involvement, industry involvement, the role of the Federal Drug Administration (FDA), various methods of health technology assessment, and some thoughts on the future for healthcare technology assessment.

Healthcare technology can be defined as all drugs, devices and medical and surgical procedures used in medical care, as well as the organizational and supporting systems within which such care is provided [8].

Rising costs

One of the primary drivers of increased costs in healthcare in the United States today is new technology. However, the cost of healthcare technology assessment is less than 0.3% of the total amount spent on healthcare, as reported by the Institute of Medicine [21]. In 2003 the US government spent $26 B on healthcare research and development. This amount was only topped in the budget by defense spending. Forty billion dollars invested in biotech ventures occurred during this same time with many efforts failing, resulting in losses in the billions of dollars [20].

Today costs are continuing to rise for new healthcare technologies. For example, the cost of development of a new knee implant system requires an investment of $10–

20 M; and would take 2–4 years before the implant is available to the market. Orthobiologics are very expensive, including cells, proteins, peptides, and genes. The costs range from $10 to $100 M with regulatory approval an additional $10 M. The new prosthetic disc, for example, has a global market of approximately $1.4 B in 5 years [10].

Medical device prices continue to rise. In the 5-year period between 1991 and 2006, manufacturers increased their list price for total hip implants on average by 171% [6]. During the same 5-year period, Medicare hospital payments went up 19%, but physician payments from Medicare declined by 13%. Profit margins for orthopaedic implants, such as plates and screws, joint replacement implants, and pedicle screws, are among the highest in the medical device industry, despite the fact that the orthopaedic device industry reinvests only 4–6% of sales revenue on research and development. When the United States is compared to other countries, it is obvious that medical device manufacturers often discount their products to other countries by 50–70% below US prices [1].

Industry

There is no doubt that successful new technology fuels business growth, allowing industries a competitive advantage. Investment growth has doubled in the last 10 years, with a world market of approximately $20 B in sales per year. The orthopaedic device industry spends approximately 4–6% of its sales ($1 B/year) on research and development [10]. The number of publicly held biotech companies has grown dramatically but their profits have been minimal. Amgen has been the largest, most profitable firm but if excluded from the publicly held biotech companies' profits, the industry would consistently be in the red. If private companies were also included in the data pool, the losses would be even greater.

Industry's new form of advertising—direct-to-consumer advertising (DTCA)—has a 5-year cost (1996–2000) of approximately $600 M–$2.5 B. The largest percentage of advertising is still directed toward the physician. Less than 50% of advertising is spent on journal advertisements [10]. Although the pharmaceutical industry has been heavily involved in DTCA for many years, only recently have medical device manufacturers begun to advertise their products directly to patients. There are important differences between prescription drugs and medical devices that impact the influence of DTCA, including substantial differences in price, decision-making, and product substitution. Although the FDA has drafted and approved guidelines for advertising related to prescription drugs, they have not yet finalized their guidelines for advertising related to medical devices. Furthermore, the FDA process for regulating DTCA in healthcare is widely perceived to be underfunded and inadequate.

Factors that influence adoption and utilization of new technology

Technology adoption and utilization is less controversial when there is a well defined clinical need—such as a severe or urgent medical problem and also when there are minimal alternatives available. However, major factors that influence utilization in technology are the financial advantages to both the physician and the hospital. Other factors that influence technology adoption and utilization include patient preferences, a strong driver; patients in the US often ask for the latest technology, often with minimal evidence of clinical benefits, believing it is the best; regulation, prestige and reputation of the advocates of the new technology; compatibility with practice style; and prevailing litigation climate. Eventually, the utilization of health care technologies is centered on physician priorities to be both effective and to use well-accepted clinical practices [15].

Adverse events in surgery

As Dr. James Weinstein wrote in an editorial in Spine, ''we must avoid using a technique or device on our patients, only to find out weeks, months or years later that it failed to achieve what we had understood from the literature'' [37]. But even more important, it is essential that physicians recognize that there is still a very high incidence of preventable adverse events in surgery. These preventable adverse events in surgery also have not changed in the last 35 years! For example in 1970 one-half of the non-fatal complications in the operating room and one-third of deaths were preventable, according to a report from the American College of Surgeons and the American Surgical Association [26]. In 1991 the Harvard Medical Practice Study reported that there were between 44,000 and 98,000 preventable deaths per year in hospitals. Orthopaedic adverse events in their study were 4% with negligence in 22% [9]. In 1999, 54% of all the adverse events in the operating room were preventable with death occurring in 5.6%. Three specialties were responsible for 67% of the surgical adverse events. They included general surgery, obstetrics/gynecology and orthopaedics. In orthopaedics, for example, hip and knee replacements' adverse events were 5.1%, in spine 6.6% [18]. Wilson also reported that 50% of adverse events in the operating room were preventable. Adverse events in surgery accounted for 35% of all adverse events in hospitals. In his report, death occurred in 2% and permanent disability in 14% [38].

A recent survey of medical errors by orthopaedic surgeons in an American Academy of Orthopaedic Surgeon survey reported approximately half the survey respondents had a medical error in the previous 6 months [39]. These errors broke down as follows:

Equipment errors: 30%—These included incomplete sets of equipment, incomplete sets of implants where the surgeons had to improvise in the operating room

Communication problems: 26%

Technical problems in the operating room where the surgeons committed errors: 13%

Medication errors: 9%

Wrong-site surgery remained high at 9%. In fact recent unpublished data by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) suggests that wrong-site surgery is increasing, in spite of the efforts of the American Academy of Orthopaedic Surgeons, the American College of Surgeons, the JCAHO and other professional organizations to eliminate this problem. Finally, *imaging problems* were responsible for 6% of medical errors by orthopaedic surgeons.

Bhattacharyya et al. [4] recently reported the results of a closed claims study reviewing 28 lawsuits with a claim of inadequate informed consent. All involved elective procedures. Three disputed the surgical site, but two involved new technology and both of them were in the spine. Risks of complications were not documented in the consent. These cases were claimants resolved 18 in favor of the defendant, 10 in favor of the plaintiff (36%). The average in orthopaedic surgery was 30%. The authors concluded that a standard should be ''surgeons (required) to disclose risks inherent to a procedure that would be deemed material by a reasonable person''[5]. They also reported that if the consent was obtained by the physician in his office, there was a significant decrease in risk. However, the risk increased if the consent was obtained in the pre-op holding area or the hospital ward.

Impact on quality

Healthcare technology is responsible for a large portion of regional variation in healthcare spending, primarily due to the lack of clinical evidence-based guidelines and/or cost-effectiveness research related to most healthcare technologies. Orthopaedic procedures are expensive and resource intensive. Regional variations of treatment in the United States are a major concern. For example the regional variations in spine surgery are well documented. There is a 40% increase in spine surgery in the United States compared to eleven other countries [11]. It is five times the rate reported in Britain. The rate in spine surgery in the United States increases linearly with per capital supply of orthopaedic surgeons and neurosurgeons. Better outcome studies are essential to reduce this variation and for a new technology to continue to be used. There have been suggestions that a threshold analysis to determine a minimal gain in clinical effectiveness is necessary in order to justify the increased cost of new technology. It has been reported, for example, that in order to justify the price of a total hip replacement two and one-half times the conventional Charnley total hip there would have to be a 90% increase in survivorship over 15 years and a 15% reduction in the cost of the revision surgery [19]. Given the high rate of clinical success that has been reported with the Charnley low-friction arthroplasty (LFA), it is unlikely that the incremental cost of any new hip replacement technology would ever be justified in terms of improvements in clinical outcomes and reductions in cost. In a similar study, Bozic et al. reported that despite widespread adoption and use, the incremental cost of a $2,000 alternative-bearing surface, such as ceramic-on-ceramic or metal-on-metal, could almost never be justified in patients over the age of 65, since the additional cost would never be recaptured by savings from lower revision rates [8]. Finally, everyone is familiar with the cascade effects of the use of MRIs and the questionable relevance of abnormalities. Deyo has stated that we still must deal with the problems of false-positive results, errors in interpretation, the overestimation of benefits, the underestimation of risks and our low tolerance of ambiguity. A common experience with the unknown significance of many MRI findings is that physicians follow the MRI with additional tests, some of which may be ill-advised and questionably ill-advised treatment.

Emerging technologies

In many cases medical technologies are accompanied by a huge price for growth. For example, Boston Scientific with Abbot Laboratories, who have $1.6 B in annual sales, purchased Guidant for $27.5 B in order to obtain the implantable cardioverter-defibrillators. This $27.5 B represented 80 times Guidant's earnings [17]. Boston Scientific obviously expected ''explosive growth'' but there have been persistent problems with the two models of defibrillators, including short-circuiting and failure to fire with more deaths reported than expected. One asks oneself why are these defibrillators still on the market if they continue to fail? Garber described the enormous potential profits, reminded us that the defibrillators have not been excluded from Medicare coverage, and that the FDA had

only been a minor obstacle to their general use, with efficacy standards not as rigorous, for example, as for drugs [17]. Because of the high prices for these devices and because of the continued risk of mortality with their use, there is an increasing scrutiny of new, expensive technology. Payers are beginning to demand well-designed and well-conducted clinical trials prior to general release of new devices. In addition because of Medicare's fiscal crisis, Center for Medicare and Medicaid Services (CMS) may not authorize continued payment. Private insurance margins are declining and they may not approve payment for such high risk, expensive technologies. As Garber pointed out, the effectiveness of these new technologies should be proven before payment is approved [17].

A common example of a new technology where physicians are extending indications for the use of a new device is the reverse total shoulder prosthesis. Indications for the use of the reverse-shoulder prosthesis are glenohumeral arthritis with an irreparable rotator cuff, irreparable rotator tear or with glenohumeral instability, or a failed arthroplasty with rotator cuff deficiency [16]. The devise has proved to be successful as salvage for these specific problems; therefore, it is widely used in these limited situations without the benefit of a prospective clinical trial. However, some surgeons are enthusiastically using this implant for osteoarthritis of the shoulder with an intact rotator cuff. This is an abuse of the procedure, i.e., being used for a situation for which it was not designed nor needed. There are other implants available. Of course, this new devise is more expensive than other previous implants on the market. Maybe in the future the reverse shoulder will be proven to be the best implant for shoulder replacement. However, because of the risks of a new technology and the increased cost of the new technology, clinical trials are needed to prove the implant's safety, efficacy and long-term success before expanding its original intended use. One of the factors that promotes the overutilization of new, expensive, and heavily promoted new technologies, such as the reverse shoulder prosthesis, is the moral hazard argument, which simply states that the parties responsibility for making decisions about which new healthcare technologies to adopt and use in a particular clinical situation, i.e., patients and providers, bear little, if any, financial responsibility for their use. Another orthopaedic example is the two-incision minimally invasive total hip procedure. Ten percent of patients have been reported to require repeat surgery. In one initial report, there was a 25% injury rate [3]. These adverse events, however, appear to have declined significantly as surgeons gained experience with the procedure. It has been suggested that the learning curve is about 40 or more cases (Rubash H, personal communication). Also there have been unconfirmed reports of many surgeons having to abandon this procedure after doing numerous cases because of their increased complication rate compared to their success in using the standard approach to total hip replacement. The two-incision total hip continues to be used in the United States, whereas its use has been observed to be declining in Europe. There are many reasons for this US experience, including its use by surgeons as a marketing tool to attract new patients. In the United States there are no published randomized prospective trials to assess the safety and outcomes of this new procedure. Because of the surgeons' large learning curve and continued struggle with this difficult procedure as well as the increased complication rate, its use is slowly diminishing. It will probably continue to be used only by surgeons who are successful with the technique and whose results remain satisfactory. But would not the public be better served if a multi-center clinical trial was completed before the procedure was available to all surgeons and the general public?

Back pain treatment remains enigmatic. In the US the fusion rates for low back pain have doubled between 1996 and 2002. As Dr. James Weinstein points out, in the 90-year history of fusion ''we remain somewhat in the dark on key questions such as indications for fusion, inability to diagnose the precise pain generator, and the frequency of adjacent segment degeneration. …MRI, and discography…have not clearly helped predict which patients…will benefit from interventions…(which) remain largely untested in well-designed randomized controlled trials'' [33]. New technologies in the treatment of low back pain include minimally invasive techniques, intradiscal electrothermal treatment (IDET), disc replacement prosthesis, intraoperative navigation, interbody cage fusions and the use of biologic growth factors such as BMP, gene therapy or a combination of drugs and devices. However, because of the increased costs of devices and procedures as well as the large amount of money consumed in the gross domestic product by healthcare, we must be able to justify any increased costs with improved clinical outcomes. Surgeons, in general, continue to be enamored with new technology and want the best and the latest for their patients, as they also want for themselves. There are often significant advantages to surgeons who are early adopters of new technologies, which effectively signal to patients and the marketplace their status as a so-called cutting edge healthcare provider. But if patient safety and clinical efficacy are truly our top priorities, we must embrace new technology by responsibly testing it and evaluating it before widespread use is advocated. Often new technology is touted as the perfect solution and later after general use we find that less than favorable results have occurred. Dr. Weinstein also points out that there are continued conflicts with the physician and the device industry, which can cloud physician judgment regarding technology

decisions [33]. Even more concerning is the fact that, in many cases, these conflicts of interest are not made transparent to patients, payers, hospitals and other providers.

Henrik Malchau has made some interesting suggestions for introducing new technology. His initial step is preclinical testing in the laboratory [23]. The next step is Clinical Step 1, a prospective randomized trial, which has the potential to identify inadequate implants or methods. It is used to determine if further clinical evaluation is necessary. Clinical Step 2 is a multi-center trial exposing new technologies to the broader orthopaedic community. It requires a sufficient number of patients and adequate statistics to prove that the new technology is safe and effective. It also should be randomized, comparing the new technology to an established gold standard technology. And clinical Step 3 is registry studies, including the very important post-market surveillance, which is required to really understand the long-term safety with increased use of an implant by large cohort studies. The Swedish hip registry is a classic example of registry post-market surveillance that has successfully diminished the rate of revision surgery for total hip arthroplasty in Sweden. Despite the success and well-documented benefits of the Scandinavian joint replacement registries, efforts to establish a similar registry in the United States have been hampered by concerns over medico-legal risk and a lack of agreement regarding who would finance the project [24, 29].

Post-market surveillance is extremely important. For example, after new drugs are released to the general public following clinical trials, half of the complications or adverse events occur and are reported as more patients use the drugs—because the large increase in numbers of patients receiving these drugs allows for full recognition of potential problems and adverse events [32]. The same problem will most likely be true for new implant technology. Only after widespread use will such a technology or implant eventually be determined to be successful or not. Market surveillance and registry studies are key for all implants, as well as drugs.

Healthcare technology assessment

Healthcare technology assessment (HTA) is the multidisciplinary evaluation of medical technologies with regard to efficacy, safety, feasibility, cost, cost-effectiveness and indications for use [8]. Complete HTA should explore the scientific, ethical, economic and social reasons for adopting a new technology and how such technologies will influence the quality of service and the distribution of resources. The primary HTA organization of the United States Federal Government is the Agency for Healthcare Research and Quality (AHRQ) [14]. The AHRQ supports healthcare quality improvements through a variety of work including evaluation of clinical services and systems, collection of HTA data (cost, cost-effectiveness, efficiency, quality, etc.), and the promotion of improvements in health system practices and evidence-based medicine. The AHRQ also acts to organize other federal HTA efforts, such as those put forth by the Quality-Inter-Agency Coordination (QuIC) Task Force (which coordinates federal quality-related healthcare activities, such as evaluation of technologies) and the US Preventive Services Task Force (which examines primary care and preventative technologies) [14, 31]. In addition, the AHRQ works to assemble evidence-based guidelines, information on the use of technology and other healthcare practices public and private sector evaluators with the National Guideline Clearinghouse (NGC, http://www.guideline.gov) [14, 31].

HTA in the United States originated primarily with federal agencies and relatively few national or regional organizations. Today, HTA in the United States is being conducted by a number of organizations in both the public and private sectors to address region- or organization-specific needs. This decentralization of HTA often lacks top-level coordination, which results in redundancy and inefficiency. While the AHRQ does act to organize some of these efforts, such as with the NGC, it also embraces such decentralization through its Evidence-Based Practice Centers (EPCs). The AHRQ obtains much of its evidenced-based research data from its 13 EPCs [14, 27, 31]. These centers are mostly contracted university-based establishments that perform focused assessments of the scientific literature in order to generate evidence reports in support of clinical practice guidelines or policies. These reports are often created at the request of both public and private sector organizations. Thus, public and private HTA efforts in the United States have developed a certain degree of mutual reliance. Unfortunately, the federal agencies involved in technology assessment remain relatively poorly funded. While evidence-based research is central to the AHRQ mission, the AHRQ recently had a reduction in annual funding for comparative-effectiveness research from $50 to $15 M. This is in contrast to annual NIH funding of $28 B [28].

Decentralization of HTA has increased with increased private sector efforts. Large healthcare providers and major healthcare product companies increasingly conduct their own technology assessment and research on clinical effectiveness and outcomes. Health plans have developed formal programs to assess technologies and procedures to facilitate payment decisions [14]. Technology assessment committees are not common among medical specialty societies. This demand for more evidence of value by the private sector, while decentralizing HTA, will continue to generate more public-private HTA cooperation [14].

Innovation is a natural outcome of revolutionary focus and will continue with great speed in healthcare. However, innovation is often accepted without clinical trials. Innovation today is left to the forces of the free market and consumer choice. But to be fair to the consumer, the patient must have full knowledge regarding all of the potential risks and benefits of a new healthcare technology or procedure in order to be able to make an informed choice for its use.

Why is innovation so hard?

According to Herzlinger, the forces that drive innovation are: the players with competing interests, funding which investors obviously need, policy with increased government regulation, the customers (patients) who want the latest, the technology itself, and the tremendous issue of accountability—including short-term safety and efficacy, the long-term cost effectiveness, and the long-term safety of the technology [20].

The barriers to innovation are numerous. They include compliance and regulatory requirements, whether or not the insurers are willing to pay, who is going to pay for the initial capital or start-up costs, the insurers, and the hospitals who often do not look at the potential savings, and who is best to accept use of the new technology [20]. Of course, then there is always the unsuspected disruptive technology that may emerge [7, 12]. In products innovations every technology carries two risks: the technology risk itself is primary and the marketplace risk is secondary.

Surgeons often continue to use new technologies without asking how they were or will be introduced to the general public, reinforcing the large problem of using a device or implant without known benefits when others in the market have proven benefits. The conclusion at a recent American Orthopaedic Association symposium on the topic was that it was more appropriate to use new technologies in clinical trials and that quicker results would occur if there were large, multi-center trials. They did recommend ''most (surgeons) should stay one fad behind and await the data needed to justify abandoning what we know works for that which may or may not be better'' [22].

Physician involvement

Physicians obviously have an important role in the development, the adoption, the utilization and choice of new technologies [8]. Physicians who use these technologies have been described as having the following characteristics: they usually have had advanced training, they are specialized or sub specialized and have a very scientific orientation to their practice, and they have access to information as well as both the clinical value and the profitability that involves the new technology. In addition, they often have increased social interaction with the medical community at professional conferences, including industry representatives. They often have close ties to medical organization and industry.

The influences on physicians' thinking and behavior include the desire for professional advancement, the reputation for providing high-quality cutting edge care, and, importantly, possible financial gain. When reimbursements are high, physicians and hospitals often move quickly to acquire use of technologies. An example is spine arthodesis in the United States. All the evidence suggests that the procedure is overused, but because reimbursements remain high, spinal fusion rates have continued to increase in the United States [13].

We believe there are changes today in physicians' professional obligations to patients. In the past physicians had to provide patients with an informed consent. Now shared decision-making is of vital importance. In the past the surgeon had no limit on his/her actions in the operating room. At present the surgeon must obtain Institutional Review Board (IRB) approval before he/she performs a new procedure in the operating room with any frequency. In the past surgical privileges were unlimited. Today surgical privileges are limited to a specialty, a sub specialty, or even in the use of a new technique or technology. In the past there was no concern for any costs by surgeons. Today costs are exceedingly important. In the past surgeons' actions were not scrutinized. Today, with increased transparency of all aspects of medical care, physicians and hospitals and healthcare facilities have increasing public exposure and their treatment outcomes are beginning to be publicly reported.

Industry involvement

Orthopaedic companies in general are committed to expensive, longer term and higher risk ventures. Their investments are often protected by patents, regulatory approval and the investment requirements. Industry is heavily involved in orthopaedics in advanced surgical technologies and techniques, computer-assisted surgery and operative planning, advanced instrumentation, resorbable fixation, prosthetic cartilage, prosthetic disc, biologics and drugs, including growth factors, gene therapy and drug–device combinations. Often, however, the profit margins associated with orthobiologics, such as new growth factors and gene products, are much lower than for metal implants, due

to much larger investments in research and development and regulatory approval that are required for biologics [10].

FDA role

Since 1976, the FDA has expanded its role to regulate not only drugs but to regulate medical devices as well [10]. Because of delays secondary to review and the political approval process, many devices may not be available to Americans in a timely fashion. An additional problem is when the FDA approves a drug or an implant, but because there is no coordination between the FDA and the payers, CMS or other private payers may elect not to pay for the new technology. Thus even though an implant is approved by the FDA, its use may be limited as health insurers refuse to pay for the technology. An example of this lack of coordination is the artificial disc. Recently, the FDA approved the prosthetic lumbar disc but Medicare had originally refused to authorize payment for the procedure for Medicare beneficiaries. Last year Medicare authorized payment for the Charite lumbar disc in patients under the age of 60 years, but not for patients over 60 years. Since Medicare includes primarily patients aged 65 years and over, it essentially is not paying for the use of this implant. Implied, however, with the approval for patients under age 60 is that other insurers can do what they want in terms of paying for the device. They cannot use Medicare as a reason for not paying for this new technology.

The FDA has two processes to evaluate new healthcare technology [10]. The 510 K or pre-market notification process requires that the implant or device have a similar or predicate implant or device on the market. The second process, known as pre-market approval (PMA), however, requires a full-scale clinical trial. The PMA process is required when there is no similar device or technology on the market. The required clinical trial is vigorous, includes a large number of patients, many with up to a 2-year follow-up, takes 4–5 years to complete and is a very expensive process. A few products that have failed after having gone through the PMA process before release to the market (again emphasizing the importance of post-market surveillance) include: first-generation surface implants of the hip, the threaded acetabulum, synthetic ligaments and the metal-back patella. The FDA is required to provide for a voluntary post-market surveillance of drugs by asking industry to follow-up on their drugs' longer-term safety, but often do not [32]. In 1990 a Safe Medical Devices'Act was passed by congress with MedWatch oversight. This legislation has also not been effective in providing continued surveillance of products on the markets because all reports from physicians, hospitals and industry are voluntary. In 2003 the American Academy of Orthopaedic Surgeons developed a member alert mechanism in to alert members about a failed implant or device or one that has been removed from the market. Again, however, this is voluntary and has not been as effective as intended to alert members about problem implants or devices.

Regarding the spine, the FDA in 1998 approved pedicle screws use by re-classifying them—Class 3 to 2. In 2004 bone cement was approved for kyphoplasty. In June 2004 the artificial disc was approved for the lumbar spine as a Class 3 device. In October of 2004, the Charite disc was cleared for marketing [10]. The FDA required surgeon education and training, but only in 2006 did Medicare eventually approve payment for the prosthetic lumbar disc in patients less than 60 years of age, but not for patients over 60 years of age. Other insurers are currently determining whether or not to pay for this new technology for the lumbar spine. Also the FDA has recently approved a cervical artificial disc and again, payers have not made decisions on whether or not to pay for this technology. Recently the Institute of Medicine reported that ''the FDA is rife with internal squabbles and hollowed by under financing, poor management and outdated regulations'' [2]. It has undergone several leadership changes and has been hampered by the conflicted political process. The Institute of Medicine made the following recommendations for drugs, and we support the same recommendations for implants and devices: FDA-approved drugs should be labeled with a black triangle for 2 years as a warning for patients that the drug is new and its risks and adverse events are not fully known. No drug advertisements would occur during this initial 2-year period on the market. In other words, the direct-to-consumer marketing would be prohibited during this period as increasing experience with the use of the drug is documented eventually allowing for a more informed public consumer. The FDA must be given authority to issue fines, injunctions and withdrawals when drug makers fail to complete their required safety studies. The FDA should thoroughly review safety of drugs every 5 years. The FDA commissioner should be appointed for 6 years and drug makers should be required to post publicly the results of all human drug trials.

Healthcare technology assessment methods

The most powerful method to assess healthcare technology is the prospective, randomized controlled trial (gold standard). It is not only most sensitive, but also very difficult and the most expensive. However, it is extremely important because these trials are needed to improve the quality of evidence for a device or implant allowing the payers and the policy-makers to approve use and payment of a new technology. An example in orthopaedics would be to determine the wear rates of different total hip designs as

scientifically accurate as possible. A very large number of patients would be randomized in the trial and the patients followed for decades in order to obtain accurate answers to this important question. Other methods include the following [8]:

- Case series/cohort studies provide insight into the use of new technology. An example would be navigation tools' effect on the accuracy of pedicle screw replacement.
- Clinical database/registries: these allow for post-market surveillance and continued assessment of the effectiveness and importantly, the outcomes of new treatments and technologies. A classic example is the Swedish National Joint Total Hip Arthroplasty Register, where after implementation the revision rate for total hip arthroplasty has been reduced from 18 to 8%. Interestingly in the United States today the revision rate for total hip arthroplasty remains about 18%.
- Epidemiological and surveillance studies: these are very useful in identifying rare events, such as malignancies associated with metal wear debris.
- Quantitative analysis (meta-analysis). These are used much more frequently today and provide summaries of the current state of knowledge from the literature. An example of the effective use of meta-analysis is the efficacy and safety of DVT prophylaxis.
- Health economic evaluations: these are extremely important today and have added a whole new dimension to health technology assessment. They assess the benefits of new and existing technology, including cost effectiveness, cost minimalization, cost-utility and cost-benefit.

Finally, there are economic modeling technologies, which are useful as an alternative to long and expensive economic trials and can be used to provide answers to the cost-effectiveness and cost-benefit and utility of a new technology.

An example of a cost effective analysis is the comparison of the use of an intramedullary nail versus external fixation for a Grade III open fracture of the tibia (Bozic K, personal communication). The cost for an intramedullary nail per case was $25,000, whereas the external fixator cost was $20,000. With a union rate of 85% for the intramedullary nail and 58% for the external fixator, the cost of a successful union, surprisingly, was $29,400 for the use of the intramedullary nail compared to $34,400 for the external fixator. Another example includes the use of cost-utility or cost-quality adjusted life years [25]. Such data has been very helpful in understanding the cost-benefit of new technologies for patients. Some examples include cholesterol testing and diet at a value of £220 versus a pacemaker of £1,100 versus a total hip replacement at £1,180. Compared to these reasonably low costs for quality-adjusted life years, the coronary artery bypass graft (CABG) procedure ranges from £2,090 to £18,830; breast cancer screening £5,780; erythropoetin treatment at £54,380 or neurosurgical treatment of brain cancer at £107,780. Bozic, in his more recent and enlightening cost effective analysis for total hip replacement, has shown that an alternative bearing total hip replacement, i.e., metal, ceramic or highly cross-linked poly, at an incremental cost of $2,000, would be cost-effective in a 50-year old patient with a cost saving over a lifetime of the patient of 19%, if associated with a 19% decrease in a 20-year failure, compared to a conventional total hip [7]. In someone over 63 years of age, he reported a lifetime cost increase regardless of the decrease in revision rate. If a bearing were only $500 more than the standard, a cost savings for patients greater than 65 years would be possible. However, over the age of 70 years, no alternative bearing associated with any additional cost would be beneficial economically. These studies underscore the importance of considering the impact of new technologies on both cost and health outcomes when performing healthcare economic analyses.

In the past, technology assessment has focused on diagnostic accuracy. In the future according to Royal, ''technology assessment will be focused on whether the use of diagnostic or treatment tools improve patients' outcomes and/or lower cost'' [30]. Cost-effective analysis of various types become primarily important and are becoming increasingly visible in many countries. However, in total hip arthroplasty, only 81 studies since 1996 include any cost-effectiveness data, of which only 8% used accepted guidelines for healthcare economic studies. Most importantly, patient safety remains a major factor and the avoidance of medical errors with the use of untested technology cannot be stressed enough.

Introducing new techonologies to the market

Dr. James Weinstein in his altruistic approach published recently in an editorial in Spine states the following: because industry is anxious to get products to market and because of the increased direct-to-consumer marketing and ''the need for swift FDA approval'' in many cases, there is usually a minimal number of studies providing solid evidence of proven efficacy, safety and effectiveness [35]. In fact he notes that industry-supported projects provide 73% of the positive results and unfunded research reports 46.2% of the positive results, but importantly only 8.2% negative results [34]. Studies are often underpowered and without clearly defined end points. There is usually inadequate follow-up and as he states, these studies ''undermine the very scientific process that has

advanced medicine'' [35]. To change the culture and the process of introducing new technology and its assessments, he proposes a national clinical trials consortium (NCTC) to ''promote and direct high-quality clinical trials less susceptible to conflict of interest'', less biased and resulting in ''more face validity'' [35]. Leaders of such a consortium would include physicians, surgeons and scientists. There would be an oversight board of independent professional societies, for example, the American Academy of Orthopedic Surgeons, The National Association of Spinal Societies, the European Spine Society (to name only 3) and other specialty societies, as well as public members. Support would be provided by industry, the payers, the FDA, the NIH, and the public. There would be a data safety monetary board composed of public members. Of major importance, this national trials consortium oversight would be extended to include post-market surveillance. Dr. Weinstein recognizes the obvious barriers—there must be willingness to do such an undertaking, that we must trust one another and commit the necessary time to the consortium. He emphasizes that we need to really decrease ''the noise of reimbursement and medical liability demands''… avoid ''fragmentation'' and ''proactively change the current process by which technology is adapted by surgeons'' [36].

Successful innovation and progress will occur more quickly and less painfully as noted by Christiansen [12] when physicians and institutions work together to embrace change, rather than fight it. But providing proven, safe, clinically effective and cost effective new technologies to the general public requires valid pre-market clinical trials as well as post-market continued surveillance with national and international registries.

Future

Many emerging healthcare technologies will dramatically affect both the cost of healthcare delivery and the health and welfare of society. In a near term i.e., 0–1 year, artificial discs, as well as ultra high field strength MRI and cardiac CT angiography are examples. In the mid-term between 1 and 4 years, permanent artificial hearts, robotic neurosurgery, cancer vaccines and focused ultrasound for lesion ablation are examples. For the longer term, i.e., more than 5 years, proton beam radiation, islet cell transplantation for diabetes, gene therapy for revascularization, and other diseases are examples. Importantly, it is necessary in each of these examples to assess the benefits, risks and costs before the new technology is available for general use by physicians. Implementation of such a comprehensive approach as described allows physicians to identify problems or opportunities that need technological solutions, such as the wear debris after total hip arthroplasty. We must examine the use and effectiveness of technologies, for example the Spine Patient Outcomes Research Trial, in order to be involved in evaluating and establishing policies, participating in the assessment of technology regulation and reimbursement, and finally to continue to scientifically contribute to medical and societal discussion of new healthcare technologies.

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